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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,887	07/24/2001	Dong Huang	P444 0001	3331

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 09/09/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/910,887	HUANG ET AL.
Examiner	Art Unit	
Sabiha Naim Qazi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 July 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 25-32 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-24 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 25-32 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>6</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 6) <input type="checkbox"/> Other: |

Election/Restrictions

DETAILED ACTION

Instant invention is drawn to sapogenins and saponins of dammarane series. Sapogenins with no hydroxyl group at C-20 compared to sapogenins that have a hydroxyl group at C-20 are claimed to be surprisingly more effective in cancer treatment. Similarly sapogenins, which do, not have a sugar moiety, are more effective than those having sugar moiety.

Claims 1-32 are pending.

Claims 1-24 are examined and others are withdrawn from consideration as non elected invention.

No claim is allowed.

Preliminary amendments are entered.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-24, drawn to dammarane sapogenins, saponins and their method of use, classified in class 514, subclass 182; class 552, subclass 502, 540; class 536, subclass 5.
- II. Claims 25-32, drawn to method of preparation of dammarane sapogenins, classified in class 552, subclass 502, 540; class 536, subclass 5.

The inventions are distinct, each from the other because of the following reasons:

Inventions of group I (in part, i.e. compounds) and group II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case process as claimed can be used to make other and materially different product.

Inventions of group I (in part, i.e. method of use) and group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In order to decrease the number of divisional applications Examiner has combined the product and the method of use to examine in group I.

During a telephone conversation with Attorney Gerald O.S. Oyen on 9/5/02, a provisional election was made with traverse to prosecute the invention of group I, claims 1-24. Applicant in replying to this Office action must make affirmation of this election. Claims 25-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 7 and 8 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims as drafted in terms of "use", however "use" is not one of the statutory classes of invention. Clinical Products v. Brenner, 1449 USPQ 475, 476 (1966).

It is suggested to re-draft the claims according to US practice.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 16-24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply.

1. What is the meaning of "cancer treatment method" in claims?
2. It is unclear what is "active ingredient in claims 17 and 18. No term as "active ingredient" is in claim 14.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims rejected under 35 U.S.C. 103(a) as being unpatentable over Hasegawa et al. (Abstract of JP 08291194) and Park, Ki (WO 97/31933).

Both the references cited above teach dammarane sapogenins and saponins, which embraces Applicant's claimed invention.

1. Determining the scope and contents of the prior art.

Kim et al. teach a dammarane glycosides Hasagawa teaches anticancer sapogenins from ginseng and their pharmaceutical compositions, (see the abstract). Park teach ginseng saponin compounds and their use as antitumor agent. See the entire document especially compound of formula (II) on page 3 and compound of formula (IV) on page 6, examples and claims. Sapogenins and saponins of dammarane series and their use as anticancer and antitumor agent are taught by both the references. Similar sapogenins and saponins as positional isomer (double bond at different position in the side chain attached at 17-position) are instantly claimed.

2. Ascertaining the differences between the prior art and the claims at issue.

Instant claims drawn to compounds and method of use differs from the references in claiming a different position of double bond in the side chain at 17-position. Even though by disclaiming certain compounds for anticipation, instant invention is considered obvious over the prior art, because instant invention is the positional isomer of the prior art.

3. Resolving the level of ordinary skill in the pertinent art.

Since instant is the positional isomer of the prior art, one having ordinary skilled in the art in search for additional dammarane sapogenins or saponins would be motivated to isolate or prepare such compounds and would expect anticancer

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activity.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Since instant sapogenins and saponins are isolated from ginseng as in instant invention and posses anticancer properties which is considered obvious to one skilled in the art at the time of invention to prepare isomers and expecting the same properties which is taught by the prior art for similar compounds.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Naim Qazi whose telephone number is 703-305-3910. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

September 6, 2002

S. QAZI
SABIHA QAZI, PH.D
PRIMARY EXAMINER